DETAILED ACTION

Status of Claims

1. Claims 1, 2, and 4-25 are current in the application. Claims 1, 2, and 4-25 are currently under examination. Claim 3 has been cancelled by Applicant.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on July 7, 2011 was filed after the mailing date of the Office Action on April 12, 2011. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, and 4-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 currently has a limitation, "at least one filtration membrane having a pore size greater than 100 Daltons." Claim 2 currently has a limitation, "at least one filtration membrane having a pore size greater than 500 Daltons." Claim 24 currently has a limitation, "at least one filtration membrane having a pore size greater than 100 Daltons." The specification as filed lacks support for these limitations; it merely states that at least one membrane may have pores of a uniform size, but does not give any limits on precisely what values the pore size of the membrane would have. (Specification, page 11, para. 2, lines 1-3)

5. Claims 4-23 are rejected as inheriting the new matter of claim 1.

6. Claim 25 is rejected as inheriting the new matter of claim 24.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 2, 4-10, 13-17, 20, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain (US 4,322,275) in view of Tye (US 3,046,211) and further in view of Akashe and Laustsen (US 5,437,774).

Regarding claim 1, Jain teaches a process for separation or concentration of organic of at least one of neutral or charged compounds in a feed solution, said process comprising the steps of: a) passing at least once a feed solution containing neutral and charged organic compounds (where the Examiner is construing blood plasma or other protein mixtures as containing neutral and charged organic compounds) (col. 6, lines 10-17) through an electrodialysis cell under electrical field, said electrodialysis cell comprising at least one charged membrane, and at least one filtration membrane (where the Examiner is construing the neutral membrane as comprising a filtration membrane) (col. 6, lines 22-32), and b) collecting separated fractions of permeate after passage of said neutral or charged compounds through said filtration membrane, each separated fraction containing separately neutral or charged compounds (col. 6, lines 44-55), wherein an ionic solution circulates between said charged membrane and said filtration membrane on the side of the filtration membrane opposed to the side on which circulates the charged compounds containing feed solution (col. 6, lines 31-33), the charged compounds passing through said filtration membrane in the ionic solution during passage in the electrodialysis cell, and neutral compounds remaining in the feed solution. (col. 6, lines 44-49)

Jain does not explicitly teach that said cell is operated with no pressure differential between the cell compartments.

Tye teaches an electrodialysis cell operated with no pressure differential between the cell compartments. (col. 3, lines 33-45) Tye teaches that this optimizes the flow rate through the membranes from the concentrating liquid to the desalting liquid. (col. 3, lines 33-36).

Neither Jain nor Tye explicitly teaches that the pH of the feed solution is adjusted to preserve the charges of said compounds.

Akashe et al teaches adjusting the pH of said feed solution to preserve the charges of said compounds (where the Examiner is construing the solubilization of proteins and the release of flavoring compounds as preservation of charges). (para. 0038, lines 1-15) Akashe et al teaches that this allows release and separation of the desired compounds (e.g. flavoring compounds into permeate and retention of protein content). (para. 0007, lines 1-8)

Furthermore, Laustsen teaches electrodialysis of proteins with a neutral filtration membrane (col. 9, lines 6-10) having a pore size which effects retention of molecules having molecular weights in the range of 200 Daltons to 200 kDaltons (which the Examiner is construing as having a pore size greater than 100 Daltons). (col. 7, lines 25-30). Prior art which teaches a range overlapping or touching the claimed range anticipates if the prior art range discloses the claimed range with sufficient specificity. See MPEP 2144(II). Laustsen teaches that this allows selective passage of the molecular species to be separated. (col. 7, lines 5-8)

Therefore, it would have been obvious to one with ordinary skill, in the art at the time of the invention, to modify the method of Jain by operating the cell with no pressure differential between the cell compartments as taught by Tye, because this would optimize the flow rate through the membranes from the concentrating liquid to the desalting liquid, (see Tye, col. 3, lines 33-36), and to further modify the method of Jain and Tye by adjusting the pH of the feed solution to preserve the charges of the said compounds as taught by Akashe, because this would allow release and separation of the desired compounds, (see Akashe, para. 0007, lines 1-8), and to use a filtration membrane having a pore size of

greater than 100 Daltons as taught by Laustsen, because this would allow retention of molecules in solution. (see Laustsen, col. 7, lines 5-8)

Regarding claim 2, Jain teaches that the said electrodialysis cell comprises, at least one cationic membrane, at least one filtration membrane, and at least one anionic membrane on the side of the filtration membrane opposed to the side of the cationic membrane. (Fig. 6, parts N and C, col. 12, lines 15-21) Furthermore, Laustsen teaches a neutral filtration membrane (col. 9, lines 6-10) having a pore size which effects retention of molecules having molecular weights in the range of 200 Daltons to 200 kDaltons (which the Examiner is construing as having a pore size greater than 100 Daltons). (col. 7, lines 25-30). Prior art which teaches a range overlapping or touching the claimed range anticipates if the prior art range discloses the claimed range with sufficient specificity. See MPEP 2144(II).

Regarding claim 4, Jain teaches that the process can be a batch recirculation process. (col. 10, lines 35-38)

Regarding claim 5, Jain teaches that said neutral or charged organic compounds are separated simultaneously during performing the process. (col. 3, lines 51-58)

Regarding claim 6, Akashe teaches that the filtration membrane may be a cellulose ester ultrafiltration membrane. (para. 0029, lines 1-10)

Regarding claim 7, Akashe et al teaches a filtration membrane with a molecular weight cutoff up to about 50,000 Daltons. (para. 0030, lines 8-12).

Regarding claim 8, Jain teaches that said filtration membrane is a charged or neutral membrane. (col. 8, lines 20-25)

Regarding claim 9, Jain teaches that the pH of the feed solution may be between 2 to 11.5 (col. 8, lines 1-15).

Regarding claim 10, Jain teaches that the compounds are of animal or vegetable origin. (col. 2, lines 42-45)

Regarding claim 13, Jain teaches that the feed solution may comprise blood plasma (which the Examiner is construing as comprising neutral organic compounds). (col. 2, lines 10-13)

Regarding claim 14, Jain teaches that the passing of step a) may be performed by continuous recirculation of the feed solution through the electrodialysis cell. (col. 7, lines 39-41)

Regarding claim 15, Jain teaches that said permeate is an aqueous solution or a salted solution thereof. (col. 6, lines 31-33 and col. 7, lines 59-60).

Regarding claim 16, Tye teaches that said permeate comprises salts at a concentration between 0.01 to 10 g/L (where the Examiner is construing the mass concentration of salt as equivalent to g/L). (col. 4, lines 44-54)

Regarding claim 17, Jain teaches that said feed solution may comprise acid compounds having pH of below 5.0, neutral compounds having pH between 5.0 to 8.0, and basic compounds having pH over 8.0 (where the Examiner is construing the blood plasma as comprising acid, neutral, and basic compounds). (col. 6, lines 10-13)

Regarding claim 20, Jain teaches that said electrodialysis cell comprises at least one cationic membrane, at least one filtration membrane and at least one anionic membrane, each membrane being separately compartmented. (Fig. 6, col. 12, lines 18-22)

Regarding claims 22 and 23, Jain teaches that the electrical field may be pulsed (alternating current) and that the electrical field may comprise pulse periods of inverted electrical field. (Fig. 6, col. 12, lines 16-18)

10. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain, Tye, Akashe, and Laustsen as applied to claim 1 above, and further in view of Canivenc et al (US 6,312,578 B1).

11. Regarding claim 11, Jain, Tye, Akashe, and Laustsen are applied as above.

Neither Jain ,Tye, Akashe, nor Laustsen explicitly teach that said compounds are physically, chemically or enzymatically hydrolyzed before performing the step of a) passing at least once a feed solution containing neutral and charged organic compounds through an electrodialysis cell under electrical field, said electrodialysis cell comprising at least one charged membrane, and at least one filtration membrane.

Canivenc et al teaches hydrolyzing the compounds before performing electrodialysis. (col. 4, lines 1-5). Canivenc et al teaches that the hydrolysis step improves the depolymerization yield and converts the oligomers into monomers. (col. 3, lines 1-4).

Therefore, it would have been obvious to one with ordinary skill, in the art at the time of the invention, to modify the method of Jain, Tye, Akashe, and Laustsen by first performing a hydrolysis of the compounds as taught by Canivenc et al, because this would improve the depolymerization yield and convert the oligomers into monomers. (see Canivenc et al, col. 3, lines 1-4).

Regarding claim 12, Jain, Tye, and Akashe are applied as above.

Neither Jain nor Tye explicitly teach that said composition flows through said electrodialysis cell at a rate of between 0.1 to 10 L/min, and said permeate at a rate of 0.1 to 150 L/min.

Canivenc et al teaches that said composition flows through said electrodialysis cell at a rate of between 0.1 to 10 L/min, and said permeate at a rate of 0.1 to 150 L/min. (col. 9, lines 14-16 and 30-32) Canivenc et al teaches that this produces a faradic yield of between 75 and 77%. (col. 9, line 45).

Therefore, it would have been obvious to one with ordinary skill, in the art at the time of the invention, to modify the process of Jain, Tye, Akashe, and Laustsen by using the composition and permeate flow rates taught by Canivenc et al, because this would produce a faradic yield of between 75 and 77%. (see Canivenc et al, col. 9, line 45).

12. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain, Tye, Akashe, and Laustsen as applied to claim 1 above, and further in view of Yamada et al (US 2006/0065279 A1).

13. Regarding claims 18 and 19, Jain, Tye, Akashe, and Laustsen are applied as above.

Neither Jain nor Tye nor Akashe nor Laustsen explicitly teaches that at least two filtration membranes are used to allow targeted molecular weight separation of said compounds in combination with charge separation.

Yamada et al teaches that at least two filtration membranes are used to allow targeted molecular weight separation of said compounds in combination with charge separation, and that each filtration membrane may have a molecular weight cut-off different from the other or others. (para. 0028, lines 7-

11) Yamada et al teaches that this allows mixtures of the non-permeate fraction and/or the membrane permeate fraction to adjust taste or flavor of the prepared flavoring agent. (para. 0027, lines 1-6)

Therefore, it would have been obvious to one with ordinary skill, in the art at the time of the invention, to modify the process of Jain, Tye, Akashe, and Laustsen by using multiple filtration membranes to target molecular weight separation of the compounds, because this would allow mixtures of the non-permeate fraction and/or the membrane permeate fraction to adjust taste or flavor of the prepared flavoring agent. (see Yamada, para. 0027, lines 1-6)

14. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jain, Tye , Akashe, and Laustsen as applied to claim 1 above, and further in view of Liang et al (US 6,649,037 B2).

Regarding claim 21, Jain, Tye, Akashe, and Laustsen are applied as above.

Neither Jain nor Tye nor Akashe nor Laustsen explicitly teaches that the pH in a compartment is different from pH of other compartments.

Liang et al teaches that the pH in an electrodialysis cell compartment may be different from the pH of other compartments (where the Examiner is construing the electrodeionization device and method of Liang et al as equivalent to an electrodialysis device and method). (col. 8, lines 29-41). Liang et al teaches that this may keep precipitating compounds in solution in the concentrating compartment. (col. 8, lines 39-42)

Therefore, it would have been obvious to one with ordinary skill, in the art at the time of the invention, to modify the method of Jain, Tye, Akashe, and Laustsen by having the pH in an electrodialysis cell compartment differ from the pH of other compartments as taught by Liang et al, because this would keep precipitating compounds in solution in the concentrating compartment. (see Liang et al, col. 8, lines 39-42)

15. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlgren (US 4,123,342) in view of Tye (US 3,046,211) and further in view of Laustsen.

Regarding claim 24, Ahlgren teaches a system for separation or concentration of organic charged compounds in a feed solution, said system comprising an electrodialysis cell comprising spaced-apart positive and negative electrodes (Fig. 1, parts 38 and 40, col. 2, lines 25-33), and at least one charged

membrane and at least one filtration membrane (Fig. 1, parts 31 and 30, col. 2, lines 25-29), the electrodialysis cell having a first compartment defined between the at least one charged membrane and the at least one filtration membrane for receiving a flow of ionic solution (Fig. 1, part 33b, col. 3, lines 38-63), and a second compartment provided on a side of the at least one filtration membrane opposite to said at least one charged membrane for receiving a flow of feed solution (Fig. 1, part 33a, col. 3, lines 38-46), the charged compounds contained in the feed solution passing under electric forces through said at least one filtration membrane into the ionic solution, the neutral compounds contained in the feed solution remaining in the feed solution. (Fig. 1, parts 31, 32, 33a, 33c, col. 4, lines 37-47).

Ahlgren does not explicitly teach that the charged compounds pass under electric forces with no pressure through the filtration membrane.

Tye teaches an electrodialysis cell operated with no pressure differential between the cell compartments. (col. 3, lines 33-45) Tye teaches that this optimizes the flow rate through the membranes from the concentrating liquid to the desalting liquid. (col. 3, lines 33-36).

Furthermore, Laustsen teaches a neutral filtration membrane (col. 9, lines 6-10) having a pore size which effects retention of molecules having molecular weights in the range of 200 Daltons to 200 KDaltons (which the Examiner is construing as having a pore size greater than 100 Daltons). (col. 7, lines 25-30). Laustsen teaches that this allows selective passage of the molecular species to be separated. (col. 7, lines 5-8)

Therefore, it would have been obvious to one with ordinary skill, in the art at the time of the invention, to modify the system of Ahlgren by operating the electrodialysis cell with no pressure differential between the cell compartments as taught by Tye, because this would optimize the flow rate through the membranes from the concentrating liquid to the desalting liquid. (see Tye, col. 3, lines 33-36), and to use a filtration membrane having a pore size greater than 100 Daltons as taught by Laustsen, because this would allow selective passage of the molecular species to be separated. (see Laustsen, col. 7, lines 5-8)

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlgren (US 4,123,342) in view of Tye and Laustsen as applied to claim 24 above, and further in view of Jangbarwala (US Pat. Pub. 2003/0213748 A1).

Regarding claim 25, Ahlgren, Tye, and Laustsen are applied as above.

Ahlgren does not explicitly teach that the charged compounds pass under electric forces with no pressure through the filtration membrane.

Neither Ahlgren nor Tye nor Laustsen explicitly teaches that said electrodialysis cell comprises at least one cationic membrane, at least one filtration membrane, and at least one anionic membrane on the side of the filtration membrane opposed to the side of the cationic membrane.

Jangbarwala teaches an electrodialysis cell comprising at least one cationic membrane, at least one filtration membrane, and at least one anionic membrane on the side of the filtration membrane opposed to the side of the cationic membrane (where the Examiner is construing the anionic-permeable membrane as an anionic-selective membrane). (Fig. 8, parts 118, 120, 181, para. 0047, lines 1-8 and para. 0048, lines 1-10) Jangbarwala teaches that this allows collection of the retentate and the cations and anions. (para. 0011, lines 20-21)

Therefore, it would have been obvious to one with ordinary skill, in the art at the time of the invention, to modify the system of Ahlgren, Tye, and Laustsen by including at least one cationic membrane, at least one filtration membrane, and at least one anionic membrane on the side of the filtration membrane opposed to the side of the cationic membrane as taught by Jangbarwala, because this would allow collection of the retentate and the cations and anions. (see Jangbarwala, para. 0011, lines 20-21)

Response to Amendment

16. The affidavit under 37 CFR 1.132 filed July 7, 2011 is insufficient to overcome the rejection of claims 1, 2, and 4-23 based upon Jain in view of Tye as set forth in the last Office action because: it include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716. Furthermore, even if Jain is interpreted

as being silent on whether the neutral membrane is a filtration membrane, it would be obvious to one of ordinary skill in the art to apply the teachings of Laustsen to the process of Jain, as both Jain and Laustsen are drawn to methods of separating proteins by electrodialysis.

Response to Arguments

17. Applicant's arguments with respect to claims 1, 2, and 4-25 have been considered but are moot in view of the new ground(s) of rejection. Furthermore, even if Jain is interpreted as being silent on whether the neutral membrane is a filtration membrane, it would be obvious to one of ordinary skill in the art to apply the teachings of Laustsen to the process of Jain, as both Jain and Laustsen are drawn to methods of separating proteins by electrodialysis.

Conclusion

18. Claims 1, 2, and 4-25 are REJECTED. Claim 3 is CANCELLED.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLLEEN M. RAPHAEL whose telephone number is (571)270-5991. The examiner can normally be reached on Monday-Friday, 9:30 a.m. to 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached at (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. M. R./
Examiner, Art Unit 1724
October 13, 2011

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1724